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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/582,971 07/07/00 PENNINGTON

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EXAMINER

KOROMA, B

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/582,971	Applicant(s) PENNINGTON, STEPHEN ROY	
	Examiner BARBA M. KOROMA	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Ph.D., Supervisory Patent Examiner at jyothsna.venkat@uspto.gov or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Restriction

2. Claims 1-30 are currently pending in this application.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11; 17-30, drawn to a method of selecting and or identifying one or more protein affinity ligands that bind to one or more proteins of interest, classified in class 435, subclass 7.1.
 - II. Claim 12, drawn to a method of generating monoclonal antibodies to one or more targeted proteins, classified in class 530, subclass 388.1.
 - III. Claim 13, drawn to a method of generating an antibody library, classified in class 530, subclass 388.1.
 - IV. Claim 14, drawn to a process for selecting desired members of an affinity ligand library, classified in class 435, subclass 7.1.

- V. Claim 15, drawn to a method of screening an affinity ligand to a protein, classified in class 435, subclass 7.1.
- VI Claims 16, drawn to a method of selecting an antibody of other protein affinity ligand, classified in class 435, subclass 335.

4. Because the inventions are of divergent subject matter, have acquired a separate status in the art, and have different and separately burdensome manual and/or computer-aided bibliographical searches, restriction for examination purposes as indicated is proper.

The inventions are distinct, each from the other because:

Groups I, IV, V, and VI are related as patentably distinct **methods of use**. They are distinguishable because group I is a method in which the selection based on one or more ligands and one or more proteins of interest. This is inherently a more complicated process because it may involve a large number of molecules, and may therefore necessitate a different experimental approach from that of group V, in which selection is to an affinity to a protein of interest. Similarly, Group IV is distinct because it involves the selection of desired members of an affinity ligand, which means that the process of selection is in fact secondary to an initial screening. In addition, group VI is distinct because it is the selection of an antibody to other protein affinity ligand. Depending on the nature of the “other” protein involved this may require special methods not applied to other groups of invention.

Art Unit: 1627

Groups II and III are related as patentably distinct **methods of making**. They are distinguishable because group II is a method of making antibodies to a plurality of targeted proteins, whereas, group III is a method of generating or making an antibody library. A plurality of targeted proteins (group II) may simply refer to several proteins. On the other hand, the term 'library' (group III) typically refers to hundreds and perhaps thousands of molecules. The latter may require a significantly differently approach, utilizing different reagents and equipment or apparatus.

Method of using (groups I, IV, V, VI) is patentably distinct from **method of making** (groups II and III) because both processes are predicated upon different objectives, entail different steps, are capable of utilizing different reagents, and result in different outcomes. Art that obviates one group does not obviate another.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. All inquiries pertaining to this case should be directed to **Barba M. Koroma**. This examiner can normally be reached at: 703 305 1915, at **9:00am to 5:00pm, Monday through Friday**.

Art Unit: 1627

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, PhD, can be reached at: 703 308 2439. The phone number for the organization where this application or proceeding is assigned is: 703 308 2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is: 703 308 1235.

Barba M. Koroma, Ph.D
Patent Examiner
AU 1627


DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
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